

Application No.: 09/147,801  
Amendment dated May 10, 2005  
In response to Examiner's Final Office Action dated February 11, 2005

REMARKS

Claims 20-28 are pending in this application.

Claims 1-5, 7, 9, 11, 15, 16 and 18 are canceled. Claims 20-28 are added.

Applicant has canceled claims 1-5, 7, 9, 11, 15, 16 and 18 without prejudice or waiver of applicant's right to file for and obtain claims directed to any canceled subject matter in future divisional or continuing applications claiming priority from this application.

Applicant has added claim 20 to recite an isolated protein comprising SEQ ID NO:4, an amino acid sequence at least 75% homologous to SEQ ID NO:4, or an antigenic fragment of SEQ ID NO:4, wherein the antigenic fragment induces or reacts with antibodies specific to Ljungan viruses. Support for this amendment is provided, e.g., on page 16, line 25 to page 17, line 34 and page 18, lines 21-22 of the specification and in original claim 4 as filed.

Applicant has added claim 21 to recite an immunogenic composition comprising the protein of claim 20 or

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claim 28. Support for this amendment is provided, e.g., on page 19, lines 17-26 and page 20, lines 12-24 of the specification and in original claim 8 as filed.

Applicant has added claim 22 to recite the immunogenic composition of claim 21, further comprising an adjuvant. Support for this amendment is provided, e.g., on page 19, lines 27-30 of the specification and in original claim 9 as filed.

Applicant has added claim 23 to recite an isolated antibody induced by or reactive with SEQ ID NO:4 or an antigenic fragment thereof, wherein the antibody is specific to Ljungan picornavirus, or an antigen-binding portion of said antibody. Support for this amendment is provided, e.g., on page 8, Table 1; page 14, 1-28; page 18, lines 1-8 and lines 19-20 of the specification and in original claim 5 as filed.

Applicant has added claim 24 to recite the isolated antibody according to claim 23 which is polyclonal. Support for this amendment is provided, e.g., on page 18, lines 5-8 of the specification.

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Applicant has added claim 25 to recite the isolated antibody according to claim 23 which is monoclonal. Support for this amendment is provided, e.g., on page 18, lines 5-8 of the specification.

Applicant has added claim 26 to recite a diagnostic kit comprising the protein of claim 20 or 28 or the antibody of claim 23, and diagnostic reagents. Support for this amendment is provided, e.g., on page 18, line 17 to page 19, line 2 of the specification and in original claim 7 as filed.

Applicant has added claim 27 to recite a method of inducing an immune response in a subject comprising administering the protein according to claim 20 or 28 or the composition according to claim 21 or 22. Support for this amendment is provided, e.g., on page 21, lines 1-14 of the specification and in original claim 13 as filed.

Applicant has added claim 28 to recite the isolated protein of claim 20, wherein the protein which comprises an antigenic fragment of SEQ ID NO:4 is at least 75% homologous to SEQ ID NO:4. Support for this amendment is provided,

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e.g., on page 16, line 25 to page 17, line 26 of the specification.

None of the amendments constitutes new matter.

Applicants requests entry of the amendments and reconsideration of the pending claims.

Applicant acknowledges with appreciation the Examiner's proposed allowable subject matter. Applicant has canceled claims 1-5, 7, 9, 11, 15, 16 and 18 (i.e., claims 1-19 would be canceled). Applicant has also added claims 20-28, which is directed essentially to the same allowable subject matter as new claims 20-26 proposed by the Examiner (see pages 5-6 of the Final Office Action).

Applicant addresses the Examiner's rejections below:

**35 U.S.C. § 112, 1st paragraph**

**Claims 4, 7, 9, 11, 15, 16 and 18**

Claims 4, 7, 9, 11, 15, 16 and 18 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking written description. Specifically, the Examiner asserts that claim 4

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and claims that depend from it lack written description in the specification for the disclaimer of the VLRTYNSSP sequence. The Examiner acknowledges that applicant was in possession of the virus isolates described in the instant application as well as the methods for isolating the structural proteins. However, the Examiner asserts that applicant was not in possession of a subunit of a virus and asserts that the specification does not disclose "the structure, formula, chemical name or physical properties of any virus subunit."

Applicant's cancellation of claims 4, 7, 9, 11, 15, 16 and 18, without prejudice, obviates the rejection as to these claims. None of claims 20-28 refer to the VLRTYNSSP sequence or to viral subunits. Accordingly, applicant requests that the Examiner withdraw this rejection.

**35 U.S.C. § 112, 1st paragraph**

**Claims 7, 9, 11, 15, 16 and 18**

Claims 7, 9, 11, 15, 16 and 18 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. The Examiner acknowledges that the specification is enabling for

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a protein comprising SEQ ID NO: 4 or an antigenic fragment of SEQ ID NO: 4 that reacts with antibodies specific to Ljungan picornavirus, for an immunogenic composition comprising such protein and fragment and for a method of inducing an immune response by administering the protein or fragment or a composition comprising them. The Examiner is of the view, however, that the application does not reasonably provide enablement for preventing and treating diseases. The Examiner also argues that an immune response produced against the protein by administering, e.g., a composition comprising the protein according to claim 20 or 28 (i.e., utilizing the method according to claim 27) may be beneficial in "ameliorating infection."

Applicant argues that administering a composition according to claim 21 or 22 or a protein according to claim 20 or 28 produces an immune response that ameliorates infection and, thereby, diseases caused by such infection. Accordingly, applicant has cancelled claims 7, 9, 11, 15, 16 and 18, without prejudice, thereby obviating the rejection as to these claims and replaced the cancelled claims with claims

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20-28. Accordingly, applicant requests that the Examiner withdraw this rejection.

**35 U.S.C. § 112, 2nd paragraph**

**Claims 4, 7, 9, 11, 15, 16 and 18**

Claims 4, 7, 9, 11, 15, 16 and 18 stand rejected under 35 U.S.C. § 112, second paragraph, as being "indefinite". Specifically, the Examiner contends that claim 4 (and therefore, claims dependent therefrom) is indefinite in reciting a sequence without a SEQ ID identifier.

Applicant's cancellation of claims 4, 7, 9, 11, 15, 16 and 18, without prejudice, obviates the rejection as to these claims. Accordingly, applicant requests that the Examiner withdraw this rejection.

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CONCLUSION

For all the above reasons, applicant requests that the Examiner withdraw all outstanding rejections and grant allowance of the pending claims.

The Examiner is invited to telephone applicant's representatives regarding any matter that may be handled by telephone to expedite allowance of the pending claims.

Respectfully submitted,

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